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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,371	05/21/2001	Hidetoshi Uemura	UEMURA 7	8300

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BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
PAK, YONG D	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,371	UEMURA ET AL.	
	Examiner	Art Unit	
	Yong D Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2001*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-36 and 41-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *20-36 and 41-53* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 of PCT/JP99/06475.

The preliminary amendment filed on May 21, 2001, canceling claims 1-19 and 37-40, adding claims 41-53 and amending claims 20-24, 29 and 31-36, has been entered.

Claims 20-36 and 41-53 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 41 and 47, drawn to a serine protease of SEQ ID NO: 2, 4, 6, 8 or 10.

Group II, claim(s) 20-24 and 42-43, drawn to DNA encoding the protein of Group I, host cell comprising said DNA and a method of producing the polypeptide.

Group III, claim(s) 25-28, drawn to a non-human transgenic animal comprising the DNA of Group II.

Group IV, claim(s) 29-30, drawn to an antibody against the protein of Group I

Group V, claim(s) 31, drawn to a method of producing the antibody of Group IV.

Group VI, claim(s) 32-35 and 44-45, drawn to a method of determining the protein of Group I.

Group VII, claim(s) 36, drawn to a diagnostic marker comprising the protein of Group I.

Group VIII, claim(s) 46, drawn to a method of screening for an inhibitor of the protein of Group I.

Group IX, claim(s) 48-49, drawn to a method of detecting a diagnostic marker of Group VII.

Group X, claim(s) 50, drawn to a method of diagnosing Alzheimer's disease or epilepsy using the marker of Group VII.

Group XI, claim(s) 51, drawn to a method of diagnosing cancer or inflammation of the brain, prostate or testicle using the marker of Group VII.

Group XII, claim(s) 52, drawn to a method of diagnosing sterility in semen or psermusing the marker of Group VII.

Group XIII, claim(s) 53, drawn to a method of diagnosing prostatic hypertrophy the marker of Group VII.

Applicants are required to elect ONE serine protease sequence of SEQ ID NO: 2, 4, 6, 8 and 10 or ONE DNA sequence encoding a serine protease of SEQ ID NO:2, 4, 6, 8 and 10.

This is not an election of species. The serine protease of SEQ ID NO: 2, 4, 6, 8 and 10 do not share a special technical feature and are independent chemical entities and require independent search in the patent and non-patent literature because the proteins have different structure and therefore different physical/chemical properties. Similarly, the DNA encoding these serine protease are independent chemical entities and require independent search in the patent and non-patent literature.

The inventions listed as Groups I-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-XIII appears to be that they all relate to a serine protease.

However, Kishi et al. (from PTO-892- NCBI Accession 1NPM B - 1998) teach a protein having an amino acid sequence wherein one to several amino acids have been deleted, substituted or added from SEQ ID NO:2, 4, 6, 8 or 10. The protein of Kishi et al. has serine protease activity and therefore can be construed as having the same property as the protein having the amino acid sequence of SEQ ID No:2, 4, 6, 8 or 10.

Therefore, the technical feature linking the inventions of Groups I-XIII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group I is a serine protease of SEQ ID NO: 2, 4, 6, 8 or 10.

The special technical feature of Group II is a DNA encoding the protein of Group I, host cell comprising said DNA and a method of producing the polypeptide.

The special technical feature of Group III is a a non-human transgenic animal comprising the DNA of Group II.

The special technical feature of Group IV is a an antibody against the protein of Group I

The special technical feature of Group V is a a method of producing the antibody of Group IV.

The special technical feature of Group VI is a a method of determining the protein of Group I.

The special technical feature of Group VII is a a diagnostic marker comprising the protein of Group I.

The special technical feature of Group VIII is a method of screening for an inhibitor of the protein of Group I.

The special technical feature of Group IX is a method of detecting a diagnostic marker of Group VII.

The special technical feature of Group X is a method of diagnosing Alzheimer's disease or epilepsy using the marker of Group VII.

The special technical feature of Group XI is a method of diagnosing cancer or inflammation of the brain, prostate or testicle using the marker of Group VII.

The special technical feature of Group XII is a method of diagnosing sterility in semen or sperm using the marker of Group VII.

The special technical feature of Group XIII is a method of diagnosing prostatic hypertrophy the marker of Group VII.

Further, the transgenic animal of Group II, the antibody of Group IV and the diagnostic marker of Group VII do not share any special technical feature because they are independent chemical entities and require independent search in the patent and non-patent literature. The methods of Group V, VI, VIII, IX, X, XI, XII and XIII do not share any special technical feature because they have different utilities and effects.

Accordingly, Groups I-XIII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak
Patent Examiner

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600